

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A process for micronization of a pharmaceutically active agent comprising the steps of:
 - (a) suspending the pharmaceutically active agent in a gaseous propellant or in a compressed gas,
 - (b) processing this suspension by high pressure homogenization, and
 - (c) obtaining dry powder upon depressurization;
whereby the particle size of the pharmaceutically active agent is reduced by the micronization process.
2. (Currently Amended) A process for micronization of a pharmaceutically active agent comprising the steps of:
 - (a) suspending the pharmaceutically active agent in a gaseous propellant,
 - (b) processing this suspension by high pressure homogenization, and
 - (c) obtaining a suspension of the micronized pharmaceutically active agent in the gaseous propellant;
whereby the particle size of the pharmaceutically active agent is reduced by the micronization process.
3. (Previously Presented) The process according to claim 1 wherein the pharmaceutically active agent micronized by said process has an average particle size between about 0.1 and about 7.0 micrometers.
4. (Previously Presented) The process according to claim 1 wherein the pharmaceutically active agent micronized by said process has an average particle size of from about 0.5 to about 5.0 micrometers.

5. (Previously Presented) The process according to claim 1 wherein the suspension formed by the pharmaceutically active agent and the compressed gas or gaseous propellant comprises one or more pharmaceutically acceptable excipient.
6. (Previously Presented) The process according to claim 1 wherein the pharmaceutically active agent is poorly soluble in water and/or chemically or thermally unstable.
7. (Currently Amended) The process according to claim 1 wherein the pharmaceutically active agent comprises at least one of pimecrolimus (33-Epichloro-33-desoxy-ascomycin), 5-[(R)-2-(5,6-diethyl-indan-2-ylamino)-1-hydroxy-ethyl]-8-hydroxy-(1H)-quinolin-2-one, 3-methylthiophene-2-carboxylic acid (6S,9R,10S,11S,13S,16R,17R)- 9-chloro-6-fluoro-11-hydroxy-17-methoxycarbonyl-10,13,16-trimethyl-3-oxo-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta-[α]phenanthren-17-yl ester, N-benzoylstauroporine, oxcarbazepine, carbamazepine, 1-(2,6-Difluoro- benzyl)-1H-[1,2,3]triazole-4-carboxylic acid amide, cox-2 inhibitors, pyrimidylaminobenzamides, camptothecin derivatives, proteins, peptides, vitamins, steroids, and bronchodilators.
8. (Previously Presented) The process according to claim 1 wherein the compressed gas comprises at least one of carbon dioxide, nitrogen, dimethyl ether, ethane, propane and butane.
9. (Previously Presented) The process according to claim 1 wherein the compressed gas is an HFA propellant qualified for human use.
10. (Previously Presented) The process according to claim 1 wherein the compressed gas is chosen from at least one of HFA134a and HFA227.
11. (Previously Presented) The process according to claim 5 wherein the pharmaceutically active excipient comprises at least one of surfactant, carrier and lubricant.

12. (Previously Presented) The process according to claim 11 wherein the surfactant comprises at least one of acetylated monoglycerides, perfluorocarboxylic acid, polyethylene glycol (PEG) sterol esters, polyethylene oxide sorbitan fatty acid esters, sorbitan esters, sorbitan mono laureate, sorbitan mono oleate, sorbitan tri oleate, sorbitan mono palmitate, propylene glycol and oleic acid.
13. (Previously Presented) The process according to claim 1 wherein the suspension of the pharmaceutically active agent in a gaseous propellant or compressed gas is processed by homogenization using static geometries.
14. (Previously Presented) The process according to claim 1 wherein the suspension of the pharmaceutically active agent in a gaseous propellant or compressed gas is processed by homogenization using a dynamic valve.
15. (Previously Presented) The process according to claim 1 wherein the suspension of the pharmaceutically active agent and the compressed gas or gaseous propellant is formed in a first stirred vessel and stored in a second stirred vessel after the micronization process.
16. (Previously Presented) A micronized pharmaceutically active agent obtained by the process of claim 1.
17. (Previously Presented) A pharmaceutical composition comprising the micronized pharmaceutically active agent of claim 16 and pharmaceutically acceptable excipients.
18. (Original) A package comprising a composition according to claim 17 and instructions to use.
19. (Previously Presented) A process according to claim 1 wherein said micronized pharmaceutically active agent is filled directly to an inhalation device.
- 20-22. (Canceled)

23. (Previously Presented) A process according to claim 2 wherein said micronized pharmaceutically active agent is filled directly to an inhalation device.
24. (New) The process according to claim 1 wherein the particle size of the pharmaceutically active agent is reduced by the micronization process to an average particle size of less than about 7 micrometers.
25. (New) The process according to claim 2 wherein the particle size of the pharmaceutically active agent is reduced by the micronization process to an average particle size of less than about 7 micrometers.